

### REMARKS

Applicant has carefully reviewed and considered the Office Action mailed on September 9, 2003, and the references cited therewith. Applicant thanks the Examiner for the telephone interview on December 2, 2003.

Claims 75-96 were withdrawn and 97-98 were added. As a result, claims 1-74, 97 and 98 are now pending in this application. New claim 97 is directed to a method of reducing the percentage of body fat in a mammal without substantially changing the mammal's weight. Support for subject matter relating to insubstantial changes in body weight can be found throughout the specification and figures, for example, in Table 2, and at page 21, second full paragraph. New claim 98 is directed to a method of reducing the percentage of body fat in a mammal by administering the indicated polysaccharide, wherein the polysaccharide gives rise to an intestinal viscosity of about 1000 mPa·s to about 3000 mPa·s. Support for subject matter relating to the polysaccharide giving rise to an intestinal viscosity of about 1000 mPa·s to about 3000 mPa·s can be found throughout the specification, for example, at page 4, lines 16-18.

### §102 Rejections of the Claims

Claims 1, 6, 9, 22-24, 36 and 37 were rejected under 35 USC § 102(b) as being anticipated by WO 98/50398 A1 by Pinto. According to the Examiner, the Pinto et al. reference discloses a beta-glucan having higher viscosity and higher molecular weights that shows benefits in weight reduction by providing longer periods of satiety (citing Pinto at page 5, lines 11-12 and page 6, lines 15-19). The Examiner asserts that Pinto et al. anticipates all elements of Claims 1, 6, 9, 22-24, 36 and 37.

Claims 1-6, 9, 13, 24 and 27 were rejected under 35 USC § 102(b) as being anticipated by U.S. Patent 6,143,731 to Jamas et al. According to the Examiner, the Jamas et al. reference discloses compositions useful in the treatment of weight loss comprising whole beta-glucans (citing Jamas at column 6, lines 65-67, column 4, lines 56-59 and column 7, lines 8-9). The Examiner asserts that Jamas et al. anticipates all aspects of Claims 1-6, 9, 13 and 24.

Claims 1, 6 and 22 were rejected under 35 USC § 102(e) as being anticipated by U.S. Publication 2003/0039708 A1 to Fleischner. According to the Examiner, the Fleischner reference discloses compositions used for weight loss comprising glucomannan (citing Fleischer

in the Abstract, at page 2, paragraph 0025 and claim 1). The Examiner asserts that Fleischner anticipates all aspects of Claims 1, 6 and 22.

Claims 38, 41 and 50 were rejected under 35 USC § 102(e) as being anticipated by U.S. Publication 2003/0019334 A1 by Portman. According to the Examiner, the Portman reference discloses compositions comprised of soluble fibers such as hydroxypropylmethylcellulose (citing Portman at page 4, paragraph 0059 and page 4, paragraph 0060). The Examiner asserts that Portman anticipates all aspects of Claims 38, 41 and 50.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ 2d 1913, 1920 (Fed. Cir. 1989). To constitute anticipation, the claimed subject matter must be identically disclosed in the prior art. *In re Arkley*, 172 U.S.P.Q. 524 at 526 (C.C.P.A. 1972). For anticipation, there must be no difference between the claimed invention and the reference disclosure, as viewed by a person of ordinary skill in the art. *Scripps Clinic & Res. Found. v. Genentech, Inc.*, 927 F.2d 1565, 18 USPQ2d 101 (Fed. Cir. 1991). To overcome the defense of anticipation, "it is only necessary for the patentee to show some tangible difference between the invention and the prior art." *Del Mar Engineering Lab v. Physio-Tronics, Inc.*, 642 F.2d 1167, 1172, (9<sup>th</sup> Cir. 1981).

Claim 1 of the present invention is directed to a method of reducing the percentage of body fat in a mammal comprising administering a sufficient amount of viscous, water-soluble, non-nutritive, non-starch, indigestible polysaccharide to the mammal for a time sufficient to reduce the percentage of body fat in the mammal.

Claim 38 of the present invention is directed to a method of reducing the percentage of body fat in a mammal comprising administering a sufficient amount of hydroxypropyl methylcellulose to the mammal for a time sufficient to reduce the percentage of body fat in the mammal.

Applicant submits that none of the prior art references disclose a method of reducing the percentage of body fat in a mammal. While some of the cited prior art references may mention reducing body weight, reduction of the percentage of body fat is not the same as reduction of body weight. When a mammal loses weight there is frequently no change in the percentage of fat in the mammal because muscle, bone or fluids may be lost instead of, or in addition to, fat.

The references provided in the Supplemental Information Disclosure Statement filed herewith clearly illustrate that weight loss and reduction in percentage body fat are distinct. For example, the article by Pawlak et al. shows that animals fed a high glycemic index (e.g. a high starch) diet had higher epididymal fat mass than animals fed a low glycemic index diet, despite comparable body weights. J. Nutr. 131:99-104 (2001). Similarly, the manuscript by Larsen et al. discloses that supplementing the diet with conjugate linoleic acid (CLA) causes loss of fat mass and increase of lean tissue mass without causing weight loss. J. Lipid Res. (Aug. 13, 2003). The article by Kamphuis further illustrates that fat mass and body weight are distinct. In particular, Kamphuis discloses that while regain of fat mass after weight loss is lowered by consumption of CLA, more fat-free mass is regained, resulting in no improvement in body weight maintenance. Accordingly, reduction of fat mass is distinct from reduction in body weight.

Applicant submits that none of the prior art references disclose methods that actually reduce the percentage of body fat in a mammal.

In particular, WO 98/50398 A1 by Pinto is limited to a disclosure of a process for producing  $\beta$ -glucans. While Pinto makes a few gratuitous comments about  $\beta$ -glucans being beneficial for the control of obesity, Pinto does not disclose that the  $\beta$ -glucans so produced are useful for reducing the percentage of body fat in a mammal. Nor does Pinto disclose that the  $\beta$ -glucans produced are a viscous, water-soluble, non-nutritive, non-starch, indigestible polysaccharide. In particular, Pinto states that the  $\beta$ -glucans have "improved properties" that relate to having better resistance to enzymatic degradation. While the Pinto  $\beta$ -glucans may be resistant to enzymatic degradation, Pinto does not disclose that the  $\beta$ -glucans are non-nutritive, non-starch, indigestible polysaccharides. In fact, Pinto obtains the  $\beta$ -glucans from barley or oat flour (see page 2, lines 21-22). While Pinto attempts to remove starch (see page 8, lines 24-26), there is no disclosure, tests or data showing that the  $\beta$ -glucans produced by Pinto are non-nutritive or indigestible. Nor does Pinto disclose that the  $\beta$ -glucans can give rise to an intestinal viscosity of about 1000 mPa·s to about 3000 mPa·s, which might be one indication that the Pinto  $\beta$ -glucans are indigestible. Hence, WO 98/50398 A1 by Pinto does not anticipate the subject matter of claims 1, 6, 9, 22-24, 36 and 37.

Applicant also submits that U.S. Patent 6,143,731 to Jamas et al. is limited to a disclosure of dietary supplements containing  $\beta$ -glucans. Jamas et al. provide data showing that the  $\beta$ -glucan

supplement can reduce cholesterol levels and lead to weight loss. However, Jamas et al. do not disclose that the  $\beta$ -glucan supplement can reduce the percentage of body fat. As described above, weight loss is not identical to reduction in body fat. The claimed subject matter is not identically disclosed in U.S. Patent 6,143,731 to Jamas et al. and differences do exist between the present invention and the Jamas et al. reference. Hence, the claims are not anticipated by U.S. Patent 6,143,731 to Jamas et al.

U.S. Publication 2003/0039708 A1 to Fleischner discloses compositions designed to support weight loss and increase energy while suppressing appetite. The compositions provided by Fleischner contain chromium, vanadium, glucomannan, green tea extract, forskolin, sodium carboxymethyl cellulose and various excipients. The Examiner has asserted that Fleischner teaches a composition for weight loss that contains glucomannan. According to Fleischner, one study indicates that administration of glucomannan leads to weight loss; other studies apparently do not show such weight loss (see Fleischner at paragraph 0025). Applicant submits that disclosure that one or more studies indicate that administration of glucomannan can lead to weight loss is not a disclosure that administration of a viscous, water-soluble, non-nutritive, non-starch, indigestible polysaccharide can lead to reduction in the percentage of body fat. Weight loss can be due to water loss, muscle loss, bone loss or a combination thereof, rather than to a reduction in body fat. Thus, the claimed subject matter is not identically disclosed in U.S. Publication 2003/0039708 A1 to Fleischner, and this publication does not anticipate the claimed invention.

As indicated above, the Examiner has rejected claims 38, 41 and 50 as being anticipated by U.S. Publication 2003/0019334 A1 by Portman. Claim 38 is directed to a method of reducing the percentage of body fat in a mammal comprising administering a sufficient amount of hydroxypropyl methylcellulose to the mammal for a time sufficient to reduce the percentage of body fat in the mammal. According to the Examiner, the Portman reference discloses compositions comprised of soluble fibers such as hydroxypropylmethylcellulose (citing Portman at page 4, paragraph 0059 and page 4, paragraph 0060). Portman is limited to disclosure of a composition for enhancing and extending satiety that includes protein, casienmacropeptide or glycomacropeptide, long chain fatty acids, and soluble and/or insoluble fibers. Applicant submits that disclosure of a composition for controlling satiety is not a disclosure of a method of reducing the percentage of body fat in a mammal. As described above, weight loss can be due to loss of fluids, muscle, bone or a combination thereof. Portman simply does not disclose that the

formulation reduces the percentage of body fat in a mammal. Hence, Portman does not anticipate claims 38, 41 and 50.

Accordingly, claims 1, 6, 9, 13, 22-24, 27, 36, 37, 38, 41 and 50 are not anticipated by WO 98/50398 A1 by Pinto, U.S. Patent 6,143,731 to Jamas et al., U.S. Publication 2003/0039708 A1 to Fleischner, or U.S. Publication 2003/0019334 A1 by Portman. Applicants respectfully request withdrawal of these rejections of the claims under 35 U.S.C. § 102(e).

### §103 Rejection of the Claims

Claims 1-37 and 52-74 were rejected under 35 USC § 103(a) as being unpatentable over U.S. Patent 6,143,731 to Jamas et al. in view of WO 98/50398 A1 by Pinto or U.S. Publication 2003/0019334 A1 by Portman. According to the Examiner, in addition to the points made in the discussion of the 102 rejections above, Jamas et al. further teaches that the beta-glucan containing composition can be included as part of a complete nutritional food (citing column 7, line 13). While Jamas et al. does not enumerate specific examples of food items, Pinto discloses that beta-glucan containing food can be developed into cereals, snacks, pasta and yogurt. Moreover, according to the Examiner, Portman teaches a nutritional composition comprising soluble fibers such as hydroxypropylmethylcellulose (citing page 4, paragraph 0059) and weight loss over a period of 6 weeks.

Claims 38-51 were rejected under 35 USC § 103(a) as being unpatentable over U.S. Publication 2003/0019334 A1 by Portman in view of Bahram et al., J. Nutrition 27: 463 (1997). According to the Examiner, in addition to the points made in the discussion of the 102(e) rejections above, Portman discloses weight loss over a period of six weeks.

Claim 1 of the present invention is directed to a method of reducing the percentage of body fat in a mammal comprising administering a sufficient amount of viscous, water-soluble, non-nutritive, non-starch, indigestible polysaccharide to the mammal for a time sufficient to reduce the percentage of body fat in the mammal.

The test for obviousness under § 103 must take into consideration the invention as a whole; that is, one must consider the particular problem solved by the combination of elements that define the invention. *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143, 227 U.S.P.Q. 543, 551 (Fed. Cir. 1985). The Examiner must also recognize and consider not only the similarities but also the critical differences between the claimed invention and the prior art. *In re*

*Bond*, 910 F.2d 831, 834, 15 U.S.P.Q.2d (BNA) 1566, 1568 (Fed. Cir. 1990), *reh'g denied*, 1990 U.S. App. LEXIS 19971 (Fed. Cir.1990). Hindsight must also be avoided. *Id.* The Examiner cannot use the Appellant's structure as a "template" and simply select elements from the references to reconstruct the claimed invention. *In re Gorman*, 933 F.2d 982, 987, 18 U.S.P.Q.2d (BNA) 1885, 1888 (Fed. Cir. 1991).

Applicant submits that none of the cited references teaches methods of reducing the percentage of body fat in a mammal that involve administering a sufficient amount of viscous, water-soluble, non-nutritive, non-starch, indigestible polysaccharide to the mammal. As described above, reduction of fat mass is distinct from reduction in body weight. Moreover, one of skill in the art cannot know whether a composition can change fat mass without testing it. For example, as shown by the Pawlak article, a diet that is high in carbohydrate leads to higher fat mass than a diet that is low in carbohydrate, while leading to no change in body weight. *J. Nutr.* 131:99-104 (2001). One of skill in the art could not have known which one would reduce fat mass. Neither can one of skill in the art predict that a composition that is reported to give rise to weight loss will cause a reduction in fat mass.

Thus, while U.S. Patent 6,143,731 to Jamas et al. provide data showing that the  $\beta$ -glucan supplement can reduce cholesterol levels and lead to weight loss, this reference does not teach that the  $\beta$ -glucan supplement can reduce percent body fat.

None of the other references cited by the examiner cure the defects present in the Jamas et al. reference. In particular, WO 98/50398 A1 by Pinto is limited to a disclosure of a process for producing  $\beta$ -glucans and provides no teaching or disclosure on percent body fat. Similarly, Portman is limited to disclosure of a composition for enhancing and extending satiety that includes protein, casienmacropeptide or glycomacropeptide, long chain fatty acids, and soluble and/or insoluble fibers, and also provides no disclosure or teaching on whether such a composition can reduce body fat. Hence, one of skill in the art would not derive from the teachings of Jamas, Pinto and Portman that administration of viscous, water-soluble, non-nutritive, non-starch, indigestible polysaccharides can reduce the percentage of body fat in a mammal.

Applicant requests withdrawal of the rejection of claims 1-37 and 52-74 under 35 USC § 103(a) as being unpatentable over U.S. Patent 6,143,731 to Jamas et al. in view of WO 98/50398 A1 by Pinto or U.S. Publication 2003/0019334 A1 by Portman.

The Examiner has further rejected claims 38-51 under 35 USC § 103(a) as being unpatentable over U.S. Publication 2003/0019334 A1 by Portman in view of Bahram et al., J. Nutrition 27: 463 (1997). As described above, Portman is limited to disclosure of a composition for enhancing and extending satiety that includes protein, casienmacropeptide or glycomacropeptide, long chain fatty acids, and soluble and/or insoluble fibers, and also provides no disclosure or teaching on whether such a composition can reduce body fat. Bahram et al. are limited to a teaching on the effects of psyllium on cholesterol metabolism in rats. Bahram et al. actually discloses that all rats studied, whether they ingested psyllium or not, gained weight (see page 466, right column, paragraph on "Body and organ weights"). Hence, there is no teaching on reducing percent body fat in either of Portman or Bahram.

Accordingly, Applicant respectfully submits that the present claims are not obvious over U.S. Publication 2003/0019334 A1 by Portman in view of Bahram et al., J. Nutrition 27: 463 (1997) and requests withdrawal of this rejection of claims 38-51 under 35 USC § 103(a).

AMENDMENT AND RESPONSE UNDER 37 CFR § 1.111  
Serial Number: 10/025633  
Filing Date: December 19, 2001  
Title: METHODS TO REDUCE BODY FAT

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Dkt: 600.523US1

Conclusion

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (516-795-6820) to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

Respectfully submitted,

DANIEL D. GALLAHER ET AL.

By their Representatives,

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.  
P.O. Box 2938  
Minneapolis, MN 55402  
516-795-6820

Date

Dec. 9, 2003

By

Robin A. Chadwick

Robin A. Chadwick  
Reg. No. 36,477

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 9th day of December 2003.

Name

Dawn M. Ryle

Signature

Dawn M. Ryle